MAY 3 0 2003

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K030593**

Applicant information:

Date Prepared:	February 19, 2002
Name:	**X-cel Contacts / Flexlens Products**
Address	2775 Premier Pkwy., Suite 600 Duluth, GA 30097
Contact Person:	Robert Chambers
Phone number:	(770) 622-9235
USA Consultant:	Martin Dalsing Medvice Consulting, Inc. 623 Glacier Drive Grand Junction, CO 81503
Phone number	(970) 243-5490 Fax (970) 243-5501 Email: mdalsing@fdapproval.com

Device Information:

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Lenses, Soft Contact, Daily Wear
Trade Name:	**Flexlens and Harrison Post Refractive Surgery (hioxifilcon A), (hioxifilcon B), (acofilcon A), (acofilcon B) Soft Contact Lens for Daily Wear (lathe-cut)**

Purpose of 510(k) submission:

ADDITION of MATERIALS ~

The purpose of this 510(k) submission is for X-cel Contacts / Flexlens Products to receive clearance to manufacture their Flexlens Soft Contact Lens for Daily Wear and Harrison Post Refractive Surgery Soft Contact Lens for Daily Wear out of four (4) additional FDA cleared hydrophilic contact lens materials. The additional materials are (hioxifilcon A), (hioxifilcon B), (acofilcon A) and (acofilcon B).

X-cel Contacts / Flexlens Products, proposes to manufacture the **Flexlens and Harrison Post Refractive Surgery (hioxifilcon A), (hioxifilcon B), (acofilcon A), (acofilcon B) Soft Contact Lens for Daily Wear (lathe-cut)**. Data supporting substantial equivalency to the predicate devices, performance, and safety and efficacy of the **Flexlens and Harrison Post Refractive Surgery (hioxifilcon A), (hioxifilcon B), (acofilcon A), (acofilcon B) Soft Contact Lens for Daily Wear (lathe-cut)** is contained in this submission.

Equivalent Device:

The **Flexlens and Harrison Post Refractive Surgery (hioxifilcon A), (hioxifilcon B), (acofilcon A), (acofilcon B) Soft Contact Lens for Daily Wear (lathe-cut)** is substantially equivalent to the following predicate devices.

- Flexlens (methafilcon A) Harrison Post Refractive Surgery Soft Contact Lens for Daily Wear manufactured by X-cel / Flexlens Products (K950294)
- Flexlens (hefilcon A) Harrison Post Refractive Surgery Soft Contact Lens for Daily Wear manufactured by X-cel / Flexlens Products (K961943)
- Flexlens 55 Soft (Hydrophilic) manufactured by X-cel Contacts / Flexlens Products (K950295)

Device Description:

The **Flexlens and Harrison Post Refractive Surgery (hioxifilcon A), (hioxifilcon B), (acofilcon A), (acofilcon B) Soft Contact Lens for Daily Wear (lathe-cut)** is fabricated from one of the above materials which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The non-ionic lens material, **hioxifilcon A**, is a copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydrosypropyl Methacrylate (Glycerol Methacrylate, GMA). It consists of 41% hioxifilcon A and 59% water by weight when immersed in normal saline solution buffered with sodium bicarbonate. The lenses are available in clear and with a blue visibility-handling tint, phthalocyanato (2) – (copper).

The physical properties of the **hioxifilcon A** lens are:

Refractive Index	1.404 (hydrated)
Light Transmission (clear)	greater than 95% T
Light Transmission (tinted)	greater than 95% T
Water Content	59 %
Specific Gravity	1.18 (hydrated)
Oxygen Permeability	18×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C), (revised Fatt method).

The non-ionic lens material, **hioxifilcon B**, is a copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydrosypropyl Methacrylate (Glycerol Methacrylate, GMA). It consists of 52% hioxifilcon B and 48% water by weight when immersed in normal saline solution buffered with sodium bicarbonate. The lenses are available in clear and with a blue visibility-handling tint, phthalocyanato (2) – (copper).

The physical properties of the **hioxifilcon B** lens are:

Refractive Index	1.404 (hydrated)
Light Transmission (clear)	greater than 95% T
Light Transmission (tinted)	greater than 95% T
Water Content	48 %
Specific Gravity	1.136 (hydrated)
Oxygen Permeability	15×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C), (revised Fatt method).

The non-ionic lens material, **acofilcon A**, is a terpolymer based on high purity Glycerol Methacrylate2,3-Dihydroxypropyl Methacrylate (GMA), with N-vinyl-2 pyrrolidone (NVP), methyl methacrylate (MMA), and 2-hydroxyethyl methacrylate (2-HEMA) and crossed-linked with Diallyl Maleate (DAM). It consists of 42% acofilcon A and 58% water by weight when immersed in normal saline solution buffered with sodium bicarbonate. The lenses are available in clear and with a blue visibility-handling tint, Color additive 'Reactive Blue 4'..

The physical properties of the **acofilcon A** lens are:

Refractive Index	1.40 (hydrated)
Light Transmission (clear)	greater than 93% T
Light Transmission (tinted)	greater than 93% T
Water Content	58 %
Specific Gravity	1.103 (hydrated)
Oxygen Permeability	25.50×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C), (revised Fatt method).

The non-ionic lens material, **acofilcon B**, is a terpolymer based on high purity Glycerol Methacrylate2,3-Dihydroxypropyl Methacrylate (GMA), with N-vinyl-2 pyrrolidone (NVP), methyl methacrylate (MMA), and 2-hydroxyethyl methacrylate (2-HEMA) and crossed-linked with Diallyl Maleate (DAM). It consists of 51% acofilcon B and 49% water by weight when immersed in normal saline solution buffered with sodium bicarbonate. The lenses are available in clear and with a blue visibility-handling tint, Color additive 'Reactive Blue 4'.

The physical properties of the **acofilcon B** lens are:

Refractive Index	1.42 (hydrated)
Light Transmission (clear)	greater than 96% T
Light Transmission (tinted)	greater than 96% T
Water Content	49 %
Specific Gravity	1.142 (hydrated)
Oxygen Permeability	15.8×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ $35^{\circ}C$), (revised Fatt method).

Pre-Clinical Performance Data: (Reference Permission to Reference letters appendix D)

hioxifilcon A
Pre-clinical performance data addressing the cytotoxicity test, systemic injection test, and ocular eye irritation test for can be referenced for the **hioxifilcon A** in Benz Research and Development's 510(k) K983773.

hioxifilcon B
Pre-clinical performance data addressing the cytotoxicity test, systemic injection test, and ocular eye irritation test for can be referenced for the **hioxifilcon B** in Benz Research and Development's 510(k) K964528.

acofilcon A
Pre-clinical performance data addressing the cytotoxicity test, systemic injection test, and ocular eye irritation test for can be referenced for the **acofilcon A** in Contamac Ltd.'s 510(k) K023349.

acofilcon B
Pre-clinical performance data addressing the cytotoxicity test, systemic injection test, and ocular eye irritation test for can be referenced for the **acofilcon B** in Contamac Ltd.'s 510(k) K024045.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a quality assurance program already in place at X-cel Contacts / Flexlens Products. The device will undergo manufacturing, packaging and sterilization procedures similar to devices currently marketed and distributed by X-cel Contacts / Flexlens Products.

The device is similar with respect to indications for use, materials, physical construction and safety & effectiveness to the predicate device, this meets the requirements per section 510(k) of the act regarding substantial equivalence and *does not raise* different questions of safety and effectiveness than the predicate devices identified above.

The following table illustrates that the production method, lens function and indications for use of the **Flexlens and Harrison Post Refractive Surgery (hioxifilcon A), (hioxifilcon B), (acofilcon A), (acofilcon B) Soft Contact Lens for Daily Wear (lathe-cut)** substantially equivalent to the predicate devices.

Substantial Equivalence Table

	CHARACTERISTICS	New Device **Flexlens and Harrison Post Refractive Surgery (hioxifilcon A), (hioxifilcon B), (acofilcon A), (acofilcon B) Soft Contact Lens for Daily Wear (lathe-cut)**	Predicate Device **Flexlens and Harrison Post Refractive Surgery (methafilcon A) (hefilcon A) Soft Contact Lens for Daily Wear (lathe-cut) K962000, K961943 & N17976**
1.)	**INDICATION**	Daily wear, Soft Contact Lens	Daily wear, Soft Contact Lens
2.)	**INTENDED USE**	The Flexlens (hioxifilcon A), (hioxifilcon B), (acofilcon A), (acofilcon B) Soft Contact Lens for Daily Wear (lathe-cut) are indicated for daily wear use for the correction of refractive ametropia and specialized use such as atypical ametropia. Examples include, but are not limited to: adult and pediatric aphakia, and irregular astigmatism created by keratoconus, trauma, or post keratoplasty. The Flexlens (hioxifilcon A), (hioxifilcon B), (acofilcon A), (acofilcon B) Harrison Post Refractive Surgery Soft Contact Lens for Daily Wear (lathe-cut) are indicated for daily wear use for the correction of refractive ametropia and specialized use such as atypical ametropia following corneal refractive surgery.	The Flexlens, (methafilcon A) Soft Contact Lens for Daily Wear (lathe-cut) are indicated for daily wear use for the correction of refractive ametropia and specialized use such as atypical ametropia. Examples include, but are not limited to: adult and pediatric aphakia, and irregular astigmatism created by keratoconus, trauma, or post keratoplasty. The Flexlens (hefilcon A), (methafilcon A) Harrison Post Refractive Surgery Soft Contact Lens for Daily Wear (lathe-cut) are indicated for daily wear use for the correction of refractive ametropia and specialized use such as atypical ametropia following corneal refractive surgery.
3.)	**PRODUCTION METHOD**	Lathe-Cut	Lathe-Cut
4.)	**HYDROPHILLIC MATERIAL/ USAN**	(hioxifilcon A) (hioxifilcon B) (acofilcon A) (acofilcon B)	(methafilcon A) (hefilcon A)
a.	Water Content	(hioxifilcon A) - 59% (hioxifilcon B) - 48% (acofilcon A) - 58% (acofilcon B) - 49%	(methafilcon A) - 55% (hefilcon A) - 45%
b.	Specific Gravity	(hioxifilcon A) - 1.18 (hydrated) (hioxifilcon B) - 1.136 (hydrated) (acofilcon A) - 1.103 (hydrated) (acofilcon B) - 1.142 (hydrated)	(methafilcon A) - 1.090 (hefilcon A) - 0.979
c.	Oxygen Permeability * Revised FATT method	(hioxifilcon A) - 18.0 (hioxifilcon B) - 15.0 (acofilcon A) - 25.5 (acofilcon B) - 15.8	(methafilcon A) - 18.8 (hefilcon A) - 16.0
d.	Light Transmittance	(hioxifilcon A) - >95% (hioxifilcon B) - >95% (acofilcon A) - >93% (acofilcon B) - >96%	(methafilcon A) - >95% (hefilcon A) - >95%
e.	Refractive Index	(hioxifilcon A) - 1.40 (hydrated) (hioxifilcon B) - 1.40 (hydrated) (acofilcon A) - 1.40 (hydrated) (acofilcon B) - 1.42 (hydrated)	(methafilcon A) - 1.40 (hydrated) (hefilcon A) - 1.43 (hydrated)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2003

X-cel Contacts/Flexlens Products
c/o Mr. Martin Dalsing
Medvice Consulting, Inc.
623 Glacier Drive
Grand Junction, CO 81503

Re: K030593
Trade/Device Name: Flexlens and Harrison Post Refractive Surgery (hioxifilcon A), (hioxifilcon B), (acofilcon A), (acofilcon B) Soft Contact Lens for Daily Wear (lathe-cut)
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: May 05, 2002
Received: May 08, 2003

Dear Mr. Dalsing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Device Name: **Flexlens and Harrison Post Refractive Surgery (hioxifilcon A), (hioxifilcon B), (acofilcon A), (acofilcon B) Soft Contact Lens for Daily Wear (lathe-cut)**

INDICATIONS FOR USE:

The **Flexlens (hioxifilcon A), (hioxifilcon B), (acofilcon A), (acofilcon B) Soft Contact Lens for Daily Wear (lathe-cut)** are indicated for daily wear use for the correction of refractive ametropia and specialized use such as atypical ametropia. Examples include, but are not limited to: adult and pediatric aphakia, and irregular astigmatism created by keratoconus, trauma, or post keratoplasty.

The **Flexlens (hioxifilcon A), (hioxifilcon B), (acofilcon A), (acofilcon B) Harrison Post Refractive Surgery Soft Contact Lens for Daily Wear (lathe-cut)** are indicated for daily wear use for the correction of refractive ametropia and specialized use such as atypical ametropia following corneal refractive surgery.

The lens may be disinfected with a chemical (not heat) disinfection system.

(PLEASE DO OT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K030593

Prescription Use X
(Per 21 CFR 801.109)

or

Over-The-Counter Use ___

(Optional Format 1-2-96)